

the warfarin and \$10,195 (12,780) in the warfarin and NSAID groups ($p < 0.01$). **CONCLUSIONS:** This analysis did not identify a difference in the odds of having a GI bleed when on warfarin or warfarin plus NSAIDs. Unexpectedly, there were significantly lower costs for the warfarin plus NSAIDs group. These results should be interpreted with caution due to the small sample size and limitations of retrospective analysis.

PG12

ADVERSE EVENTS OF PROMETHAZINE AND ONDANSETRON IN YOUNG CHILDREN AND WOMEN OF CHILD-BEARING AGE: A PHARMACOVIGILANCE STUDY BASED ON THE FDA ADVERSE EVENT REPORTING SYSTEM

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OBJECTIVES: Pregnant women may use promethazine or ondansetron for nausea and vomiting during pregnancy (NVP). The long-term safety and its potential risks on the fetus and newborns are widely unknown. Promethazine has a black boxing warning for contraindicating its use in infants and young children. The purpose of this study was to quantify and describe adverse events (AEs) related to these two medications in child-bearing age women and young children. **METHODS:** The data source was the FDA's Adverse Events Reporting System database from 1997 to 2006. Using a retrospective data analysis, AEs for all patients with study drugs were compared to that for children ages 0–6 years old and women of child-bearing age (CBA) 15–50 years old. The annual frequencies of AEs for both study drugs were analyzed and stratified by age group and gender. The related AEs were categorized by clinical outcomes, pregnancy outcomes, route of administration, and duration of therapy. **RESULTS:** A total of 392,229 AEs for promethazine and 282,056 AEs for ondansetron were reported. Of those, 13.7% of ondansetron and 22% promethazine AEs were for CBA women with the peak for age 35–50; while 13.1% ondansetron and 13.8% promethazine AEs were for children age 0–6 with the peak for age 0–2. There were 23.68% and 13.54% AEs related to promethazine and ondansetron long-term use (greater than 90 days) among CBA women, respectively. The most common routes of administration were oral and intravenous. For CBA women, the frequent AE pregnancy outcomes were maternal complications (26%), premature labor (9%), maternal drugs affecting fetus (8%) and spontaneous abortion (4%); while the most frequent AEs for children were neonatal respiratory arrest (0.25%) and neonatal apneic attack (0.17%). **CONCLUSIONS:** AEs of promethazine and ondansetron among children and CBA women are common. The risk of their off-label use for the long-term treatment of NVP should be recommended with cautions.

PG13

PREVALENCE, COSTS AND SERVICES OF COMORBID CONDITIONS ASSOCIATED WITH FUNCTIONAL DYSPEPSIA

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OBJECTIVES: The etiology of functional dyspepsia (FD) is debated. However, no published data exist on the associated co-morbid conditions with FD. This study aimed to assess the prevalence, services, and costs related to co-morbid conditions associated with FD. **METHODS:** Retrospective database analysis on a 4-year study period, from January 1, 2001, through December 31, 2004 using payroll data and adjudicated health insurance medical and prescription claims on more than 300,000 employees. Study comparisons were performed among employees with FD and propensity-score-matched employees without FD (controls). Outcome measures included the prevalence, costs and utilization of health services for various comorbid conditions as defined by the Agency for Healthcare Research and Quality (AHRQ). **RESULTS:** Employees in cohort FD (N = 1669) and a 50:1 matched control-cohort (N = 83,450) were compared. Employee with FD were more likely to have all major diagnostic categories (MDC) including digestive system, blood and blood forming organs, mental disorders, infections and parasitic disease, etc. except pregnancy and prenatal related disease, compared to matched controls. The top MDC prevalence ratios between the two groups were for digestive systems (6.3:1), blood and blood form organs (2.6:1), mental disorders (2.1:1), and infectious & parasitic disease (2.0:1). More interestingly, 18 of the top 30 most prevalent AHRQ "specific" categories were non-specific with the terms like "other" or "undefined" in the title. Moreover, annual medical costs for the FD cohort were greater than for controls in 155 (59%) of the 261 AHRQ's Specific Categories and significantly greater ($P \leq 0.05$) in 76 categories (29%). Similarly, the services were greater for 179 (69%) of the 261 Specific Categories and significantly greater ($P \leq 0.05$) in 110 categories (42%). **CONCLUSIONS:** This study showed excess comorbidity in employees with FD compared to employees without FD, might be a major determinant factors for excess health-care services and health-care costs of functional dyspepsia.

SYSTEMATIC REVIEW AND META-ANALYSIS OF PUBLISHED RANDOMIZED CONTROLLED TRIALS COMPARING THE EFFICACY OF PEGINTERFERON-ALPHA-2A VERSUS PEGINTERFERON ALPHA-2B BOTH PLUS RIBAVIRIN IN CHRONIC HEPATITIS C PATIENTS

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OBJECTIVES: Hepatitis C affects approximately 180 million people worldwide. It is one of the main causes of liver disease and is the predominant etiology for liver transplantation. This study performs a systematic review and meta-analysis of published randomized controlled trials comparing efficacy of peginterferon-alpha-2a versus peginterferon-alpha-2b both in association with ribavirin in order to assess which is more effective in the treatment of HCV infection. **METHODS:** A thorough search in MEDLINE, Lilacs, Cochrane library and Embase databases was conducted in the last quarter of 2009. Manual searches in specialized websites were also carried out. Included studies were those which evaluate treatment efficacy of peginterferon alpha-2a versus peginterferon alpha-2b both plus ribavirin for hepatitis C treatment in naive patients or nonresponders to other therapies not co-infected with HIV. According to heterogeneity test, a fixed or a random-effect models was adopted for meta-analysis. **RESULTS:** A total of 570 citations (databases citation without duplicates plus manual searches) were found but only seven met the inclusion criteria: 1) Ascione, 2009; 2) Rumi, 2009; 3) McHutchison, 2009; 4) Yenice, 2006; 5) Scottot, 2008; 6) Kolakowska, 2008; 7) Berak, 2007. All studies are randomized controlled trials. Overall, peginterferon-alpha-2a has shown higher sustained virological response (SVR) as compared to peginterferon-alpha-2b: 51.7% versus 42.4% (RR = 1.23, IC 95% 1.10 – 1.38, assuming a fixed-effect model). For genotypes 1/4: 42.1% versus 33.3% (RR = 1.11, IC 95% 1.02 – 1.20, assuming a fixed-effect model) and for genotypes 2/3: 79.2% versus 73.8% (RR = 1.11, IC 95% 1.01 – 1.22, assuming a fixed-effect model). **CONCLUSIONS:** These findings suggest that peginterferon-alpha-2a is associated with a higher clinical response than peginterferon-alpha-2b indicating that it should be used as the standard-of-care therapy. Our results are in line with another recent published systematic review (Awad, 2009) which concluded that peginterferon-alpha-2a has a higher SVR as compared to peginterferon-alpha-2b, with similar safety profile.

PG15

A META-ANALYSIS OF THE 5-HT₃ RECEPTOR ANTAGONISTS USE IN POST-OPERATIVE NAUSEA AND VOMITING PROPHYLAXIS

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OBJECTIVES: To investigate whether the 5-HT₃ receptor antagonists—ondansetron, granisetron, tropisetron, and dolasetron—used for the prevention of post-operative nausea and vomiting (PONV) differ in efficacy. **METHODS:** A meta-analysis was conducted using published studies. A systematic literature search within Pubmed and the Cochrane Library for randomized, controlled, double-blinded studies measuring efficacy in terms of PONV prophylaxis was conducted. The odds of patients exempted from PONV and post-operative vomiting (POV) within each study arm 24 hours after surgery were the primary indices of drug efficacy. Indirect comparisons using random effect models were conducted. Subgroup analyses excluding controversial studies and controlling amount of dose and administration route were also conducted. **RESULTS:** A total of 82 studies were identified, representing 15,709 patients. In terms of preventing PONV, the analysis indicated that granisetron was statistically significantly better than ondansetron (odds ratio(OR) = 1.46, 95% confidence interval(CI):1.08–2.00) and dolasetron(OR = 1.56, 95%CI: 1.03–2.34); no other statistically significant relationships comparing either two of the four drugs were found. In terms of preventing POV, the four antiemetic drugs had comparable efficacy: granisetron showed similar efficacy as compared to ondansetron(OR = 1.61, 95%CI: 0.99–2.63), tropisetron(OR = 1.70, 95%CI: 0.95–3.05) and dolasetron(OR = 1.35, 95%CI: 0.78–2.27); ondansetron exhibited comparable efficacy as compared to tropisetron(OR = 1.06, 95%CI: 0.63–1.79) and dolasetron(OR = 0.84, 95%CI = 0.52–1.31); tropisetron and dolasetron were also similar in efficacy(OR = 0.80, 95%CI = 0.44–1.37). Subgroup analyses also found that the four drugs did not differ in efficacy. All 5-HT₃ receptor antagonists were statistically significantly better than placebo. **CONCLUSIONS:** With respect to PONV prophylaxis, granisetron was statistically significantly better than ondansetron and dolasetron; ondansetron, tropisetron, and dolasetron exhibit similar efficacy. With respect to POV prophylaxis, ondansetron, granisetron, tropisetron, and dolasetron appeared to have comparable efficacy.

PG16

TEMPORAL CHANGES IN SURGICAL PROCEDURES FOR MANAGEMENT OF DIVERTICULAR DISEASE

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OBJECTIVES: Research has suggested that admissions for diverticular disease (DD) are on the rise in Western countries, particularly among a younger patient population. However, relatively little is known about how this increase has impacted the use of surgical procedures for the management of DD. The goals of this study were a) to determine temporal trends in the use of surgical procedures (laparoscopic colectomy [LC] and open colectomy [OC]) for DD, and b) to investigate temporal changes in